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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Veterinary Laboratories, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous parasites.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, filed ANADA 200–341 that provides for oral use of SPARMECTIN–E (ivermectin) Liquid for Horses for the treatment and control of various species of internal and cutaneous parasites. Veterinary Laboratories' SPARMECTIN–E Liquid for Horses is approved as a generic copy of Merial Ltd.'s EQVALAN (ivermectin) Oral Liquid for Horses, approved under NADA 140–439. The ANADA is approved as of March 8, 2004, and the regulations are amended in 21 CFR 520.1195 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1195 [Amended]

■ 2. Section 520.1195 is amended in paragraph (b)(1) by adding "000857" in numerical sequence.

Dated: 4/23/04

April 23, 2004.

Catherine P Beck

Catherine P. Beck,
Acting Director,
Center for Veterinary Medicine.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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